ance. **CONCLUSIONS:** The following of protocols and guidelines for hernia repair has been shown to improve patient outcomes and reduce costs but the degree of uptake is variable. This suggests that there is scope for greater protocol/guideline adherence and resultant cost savings in hernia repair

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THE INFLUENCE OF "HAS" HAUTE AUTORITE DE SANTE IN THE REIMBURSEMENT DECISIONS IN FRANCOPHONE COUNTRIES: THE CASE OF NORTH AFRICA REGION

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OBJECTIVE: France has large markets for pharmaceuticals in Algeria; moreover, Algerian authorities look to France for reference pricing. In recent times, the HAS is increasingly the influential health technology assessment (HTA) agency. French speaking countries are referencing and following the HAS decisions. The main objective of this study is to assess the HAS influence in North Africa region (Morocco, Algeria, Tunisia) in their reimbursement decisions. **METHOD:** To have a comprehensive study, a sample of medicines was determined, and these drugs had obtained positive recommendation by HAS during a period from January 2013 to December 2013.Then, the recommendation from HAS were matched with the North African decision. **RESULT:** Total drugs approved for their first inscription were 258, where one drug obtained ASMR II, 12 obtained ASMR III, 13 noted ASMR IV and 232 ASMR V. When we have analyzed the common reimbursement decision taken according the level of ASMR We have observed that Morocco reimburse the drugs product with ASMR III and ASMR IV. However Algeria and Tunisia reimburse less the medicines with ASMR IV and V **CONCLUSION:** This study demonstrates that the discordance between countries reimbursement decisions. In most cases it may reflect the differences in the decision making process and in their constraint budget: Payers in Morocco are following HAS recommendation whereas Tunisia and Algeria there are following less HAS decisions.

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TRACKING DRUG UTILIZATION DATA TO ENABLE CONDITIONAL REIMBURSEMENT OF MEDICINES OR SPECIFIC INDICATIONS IN ROMANIA: ANALYSIS OF THE REQUIREMENT FOR AN EFFECTIVE IMPLEMENTATION

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BACKGROUND INFORMATION: In 2014, Romania adopted a new legislation requiring Health_Technology_Assessment (HTA) as mandatory step in the drug reimbursement listing. The HTA System is a score-card, the drug/ a certain indication can be unconditional (80 – 145 points), or conditional approved (60-79 points). Conditional approved indications are reimbursed only if they are included in a cost-volume/cost-volume-result contract (CV/CVR) with the National Payer,- requiring the tracking of drug utilisation data on indication. This could lead to differentiated pricing, depending on the benefit the product provides in different indications (Multiple Indication Pricing-MIP). One single unit price could be not relevant for all indications (e.g in oncology), especially when the same drug has both unconditional and conditional reimbursement. **APPROACH:** Under MIP, drug utilisation would be tracked; the price of medicine per indication would be defined according to the benefit of the drug in that indication. Two approaches could be used: leverage existing national data collection by the National Payer, additionally collecting data like indication, treatment status, result, etc. by a separate module in the Hospital Information System or use e-health/electronic patient records. Implications: Required minimum data fields, data format and attributes must be defined. Data must be complete, consistent, available, allowing for validity checks. Marketing Authorization Holder (MAH) must receive reports containing information (anonymised and aggregated) on drug utilisation. To be defined: timing between data capturing and data availability, timing for paybacks, absorption of costs for data generation and capturing, error handling. **RECOMMENDATIONS:** Conduct pilot with a representative oncology clinic, set a methodology for collection, validation and use of data, generate reports, demonstrate the utility in managing CV/CVR. Scale up the project at national level through the National_Health_Insurance_House. **CONCLUSION:** Developing a system to identify drug utilisation on indication, could support implementing conditional reimbursement schemes by the Payer and increase patient access to drugs.

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TARGETED COMBINATION REGIMES IN ONCOLOGY CHALLENGES FOR PRICING AND REIMBURSMENT IN SWITZERLAND: ANALYSIS OF THE IMPLICATION AND OPERATIONAL REQUIREMENT FOR IMPLEMENTATION OF AN INDICATION CODE

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BACKGROUND INFORMATION: Targeted Combination Regimes (TCRs) could significantly improve outcomes for cancer patients in future as drugs with different and complementary mechanisms of action often act synergistically to improve treatment results. Despite the potential benefits of TCRs there are also challenges associated with them. Several combination therapies involve more than one Marketing Authorization Holder, adding the cost of two medicines on top of each other combined with potentially longer therapy duration could make the funding of such TCRs unsustainable. The Federal_Office_of_Public_Health (FOPH) currently commands price negotiation at brand level, resulting in a single price per product, however in the future a more flexible pricing system might be required in order to enable fast patient access while making sure TCRs remain effective, expedient and economical. **APPROACH:** One approach could be the introduction of an indication code on the billing process. The indication code could help health insurance companies to identify TCRs and allow a fast reimbursement through a simple and standardised process. Flexible pricing models would make sure that TCRs remain economical. **Implications:** Patients would have to agree that information on their condition (e.g. indication, molecular profile, therapy) would be captured on the billing process. The indication code would have to be encrypted by the health insurer. The IT systems of health insurers and hospitals need to be adapted. **RECOMMENDATIONS:** A working group led by the pharma industry association and major health insurers (including pharma companies, hospital administration and oncologists) will set up pilots with oncology clinics to test the feasibility of implementing an indication code and work on sustainable pricing models for TCRs. **CONCLUSION:** Goal would be a standardised processing of the remuneration for TCRs based on indication code and the underlying pricing model. For scale up the FOPH would have to mandate the adoption of the approach at national level.

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BREXIT AND GREXIT: IMPLICATIONS FOR THE PHARMACEUTICAL INDUSTRY

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BACKGROUND: The prospects of Brexit (UK exit from the EU) and Grexit (Greek exit from the Eurozone) have significant implications for the European pharmaceutical industry. In recent years, exiting the EU has been actively debated in the UK. While not a member of the Eurozone, the UK is a key member of the EU trade bloc. The UK government plans to hold a referendum by 2017; recent polls indicate 35-45% of Brits support withdrawal. In contrast, Greek withdrawal from the Eurozone may occur if the government is unable to reach an agreement with their creditors on the repayment of Greek sovereign debt. Failure to meet a €1.6 billion payment to the IMF at the end of June 2015 may result in Eurozone withdrawal. **IMPACT:** As an EU member state, the UK forms a significant component of international reference pricing baskets for many other states; an arrangement which may or may not continue in the event of Brexit. Despite the independence of the British pound, Brexit may lead to further regional price disparity due to currency fluctuations. Both Brexit and Grexit are likely to have a significant impact on parallel trade amongst EU member states (parallel imports represent ~20% of UK drug sales, whereas exports for parallel trade account for ~12% of the Greek pharmaceutical market). Additionally, Grexit may impact the purchasing power of Greeks and their government's ability to fund healthcare access to medicines. **METHODOLOGY:** Navigant conducted qualitative interviews with payers and budget holders to understand expectations of the impact of Grexit and Brexit, anticipated strategies in response to these withdrawals, the level of disruption to pharmaceutical supply and potential drug shortages. **CONCLUSIONS:** Additional monitoring and appropriate planning is essential. The high level of uncertainty requires further consideration; Brexit and Grexit present significant implications to a broad array of stakeholders.

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THE TRENDS IN ORPHAN DRUG AUTHORISATION AND APPROVAL IN EUROPE AND IN THE UNITED STATES - A RETROSPECTIVE STUDY (2005-2014)

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BACKGROUND: There are differences across the world in the definitions used to classify an orphan drug (OD), especially with respect to the prevalence of the disease justifying the orphan status and, the estimation of the population affected by the disease. **OBJECTIVE:** To identify the number of medicines which have been granted orphan designation in the United States (US) and European Union (EU), and analyse the approval trends over a ten-year time horizon. **METHODS:** All ODs authorised by the European Medicines Agency (EMA) and approved by the US Food and Drug Administration (FDA) were identified on the 1st May 2015 by downloading the databases available from their respective websites. Duplicates were removed in both cases using non-proprietary name and the lists were filtered to capture the period from 01/01/2005 to 31/12/2014. **RESULTS:** The databases downloaded from the EMA and FDA had n=93 and n=237 results respectively. Removing the duplicates reduced these to n=91 and n=197 respectively. Filtering the list to select ODs authorised between the 01/01/2005 and 31/12/2014 gave final values of n=74 and n=189 respectively. ANALYSIS: The number of ODs approved significantly increased in numbers between the years 2005 and 2014 in the US and in the EU. In 2014 the EMA authorised 5 times as many ODs as they did in 2005 (15 vs 3 respectively) and a similar trend was observed in the US, where in 2014 the FDA authorised twice as many ODs as they did in 2005 (30 vs 14). **CONCLUSIONS:** In 2005 the number of ODs authorised was significantly lower than that of 2014 and the designation of orphan diseases and approval of ODs was rare. 10 years on and gaining OD status for a sub population based rare disease appears from the outside to have become an objective for a number of pharmaceutical companies.

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INTRODUCTION OF FORMAL RISK SHARING AGREEMENTS (RSA): A PROMISING SOLUTION FOR SUSTAINABLE AND PREDICTABLE PHARMACEUTICAL EXPENDITURES IN BULGARIA

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OBJECTIVES: To evaluate the potential for RSA implementation in Bulgaria and to outline the necessary legislative changes. **METHODS:** A literature review of the existing in EU RSA schemes and review of the local legislation were done to identify the laws and regulations intended for changes. **RESULTS:** Bulgarian government has recently carried out major changes within the Health Insurance Act. The adopted texts introduced a "no discount - no reimbursement" rule, creation of HTA body and formal HTA assessment for all new and existing medicines with re-assessment every three years. The new HTA body is expected to adopt a threshold for cost-effectiveness. Companies will be allowed to provide discounts for new medicines before reimbursement decision hence to influence the cost-effectiveness. The new measures are focusing mainly on the prices of the medicines, as were the old one (voluntary discounts to NHIF). The National Health Insurance Fund (NHIF) should consider other options which will give them opportunity for broader based negotiations with the MAHs. As such option could be considered the implementation of RSA